

**REMARKS**

Upon entry of this amendment, claims 1, 5, 17-18, 20 and 21 will be amended, so that claims 1-29 will remain pending.

By the amendment herein, claim 1 has been amended to recite "a water-soluble lozenge base". Support for this amendment is present in Applicant's originally filed application, including Example 1, such as at page 10, lines 9-28, where all constituents of the lozenge base are dissolved in water. Moreover, at page 13, beginning at line 22, fresh lozenge test solution is obtained using distilled water.

Moreover, the claims have also been amended to place the claims more in accordance with U.S. practice.

Reconsideration and allowance of the application are respectfully requested.

**Information Disclosure Statements**

Applicants express appreciation for the inclusion with the Office Action of initialed copies of the Forms PTO-1449 submitted with the Information Disclosure Statements filed October 26, 2006, July 10, 2008 and November 21, 2008, whereby the Examiner's consideration of the Information Disclosure Statements is of record.

**Priority**

Applicant acknowledges the Examiner's indication regarding the parent PCT application, and remind the Examiner that PCT/EP03/13873 entered the U.S. national stage and was awarded Application No. 10/582,223, and published as US 2007/0081950 A1. The Examiner is requested to review the file wrapper of this parent application at the Patent and Trademark Office,

including the Office Actions mailed therein. If the Examiner needs any documents, the Examiner is requested to contact the undersigned.

### **Restriction Requirement**

The Restriction Requirement has been maintained and has been made final. The claims of Group I, i.e., claims 1-15 and 22-29, are examined on the merits, and Group II, i.e., claims 16-21, stand withdrawn from consideration as being drawn to a non-elected invention.

Applicants notes that US 2002/0061282 is referenced in the Restriction Requirement, but not used in any rejection of the claims.

Applicants are permitting the non-elected claims to remain pending subject to rejoinder upon allowance of the elected subject matter.

### **Response To Art Based Rejections**

The following art based rejections are set forth in the Office Action:

(a) Claims 1-4, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 01-172315 (including partial translation of Example 7) to Lion Corp. (hereinafter “Lion Corp”) as evidenced by U.S. Patent No. 5,156,845 to Grodberg (hereinafter “Grodberg”).

(b) Claims 1, 6-9, 11, 14, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp as evidenced by Grodberg, and in view of U.S. Patent No. 6,682,722 to Majeti et al. (hereinafter “Majeti”).

(c) Claims 1, 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over to Lion Corp as evidenced by Grodberg, and in view of U.S. Patent No. 6,685, 912 to Holme et al. (hereinafter “Holmes”).

(d) Claims 1, 5, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp as evidenced by Grodberg, and in view of U.S. Patent No. 6,703,000 to Ning et al. (hereinafter "Ning").

Initially, Applicant notes that a machine English translation of JP 2580661B (which is the granted patent related to Lion Corp) as downloaded from the JPO website is being submitted herewith. Applicant is also submitting a Form PTO-1449 listing this English translation. The Examiner is requested to confirm consideration of the English translation by including an initialled copy of the form with the next communication from the Patent and Trademark Office.

Applicants submit that a fee should not be necessary for consideration of this English translation, because the document has been considered by the Examiner and is used in the rejections set forth in the Office Action. However, authorization is hereby provided to charge any fee necessary for consideration and entry of this document into the record to Deposit Account No. 19-0089.

Moreover, in response to these grounds of rejection, Applicant submits that Lion Corp does not teach or suggest the subject matter recited in Applicant's claims for at least the reasons set forth herein, and none of the documents used in the rejections of record, whether taken alone or in any combination, overcomes the deficiencies of Lion Corp.

Lion Corp relies on the chemical action of a ketone compound and/or an epoxy compound for chemical tooth whitening. The composition may be used in different delivery forms such as a toothpaste, a mouth wash, a troche or a chewing gum. In addition, the composition may comprise a variety of optional constituents such as abrasives, including amongst others calcium pyrophosphate. The only example featuring calcium pyrophosphate

relates to a chewing gum composition. Therefore, Lion Corp fails to disclose a lozenge composition comprising calcium pyrophosphate as a tooth whitening agent.

Still further, Lion Corp is silent with respect to a lozenge composition comprising calcium pyrophosphate wherein the lozenge base is water-soluble.

Grodberg is used in the anticipation rejection and obvious rejections as asserted evidence of gum bases being used as lozenge bases. However, Grodberg relates to a lozenge for overcoming dry mouth condition. In Example 1, which is referred to in the rejection, the lozenge composition comprises gum base. This, however, does not equate to lozenge base, let alone a water-soluble lozenge base. Unlike lozenge base, gum base is, by definition, water-insoluble. This well-known property of gum base is further evidenced by column 3, lines 14-18, of Grodberg, where it is explained that the incorporation of gum base leads to a chewing gum residue after dissolution of the water-soluble lozenge constituents.

Accordingly, it is readily apparent that Lion Corp does not teach each and every feature recited in Applicant's amended claims, so that the anticipation rejection should be withdrawn.

Regarding the obviousness rejections, Applicant directs the Examiner's attention to the machine English translation of JP 2580661B. With respect to the prior art, Lion Corp discusses at length the disadvantages of tooth-whitening agents based on mechanical work of abrasives. These are considered in the context of applying mechanical action, disclosing that there is an increased danger of wearing out a tooth, as see, the Detailed Description, second paragraph. As a solution, Lion Corp proposes a "chemical operation" making use of a ketone compound and/or an epoxy compound. The composition may optionally contain other ingredients like an abrasive such as calcium pyrophosphate. However, the choice of the "proper ingredient" is subject to the delivery form (page 2, beginning at line 25).

In other words, the delivery form in Lion Corp, for example tooth paste, mouth wash, troches, or chewing gum, determines the choice of additional ingredients. Abrasives, such as calcium pyrophosphate are, however, exclusively mentioned in terms of mechanical action, that is with respect to delivery forms such as chewing gum. Significantly, the only example mentioning calcium pyrophosphate (Example 7) relates to a chewing gum composition. By contrast, the example relating to a troche composition (Example 6) is silent on any form of abrasives, in particular on calcium pyrophosphate. This is perfectly in line with the general recommendations in Lion Corp on mechanical/masticatory action and the corresponding choice of optional ingredients.

Therefore, Lion Corp does not provide any teaching or suggestion of a tooth whitening lozenge composition comprising a water-soluble lozenge base and calcium pyrophosphate. Lion Corp does not even remotely acknowledge a beneficial effect of abrasives in non-masticatory delivery forms, such as lozenges. The tooth whitening effect of a calcium pyrophosphate containing lozenge is therefore highly surprising and non-obvious in view of the cited prior art.

Still further, Applicant submits that any combination of the cited documents would not arrive at the subject matter recited in Applicant's dependent claims at least for the reasons set forth above, and for the additional features recited in dependent claims in combination with the subject matter from their parent claims.

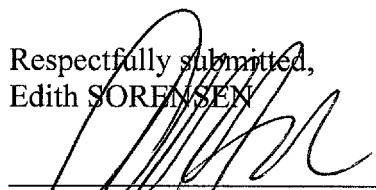
For at least the reasons set forth above, the rejections of record should be withdrawn with the early mailing of the Notices of Allowance and Allowability.

**CONCLUSION**

Entry and consideration of the present amendment, reconsideration of the Office Action, and allowance of the present application and all of the claims therein are respectfully requested and believed to be appropriate.

Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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